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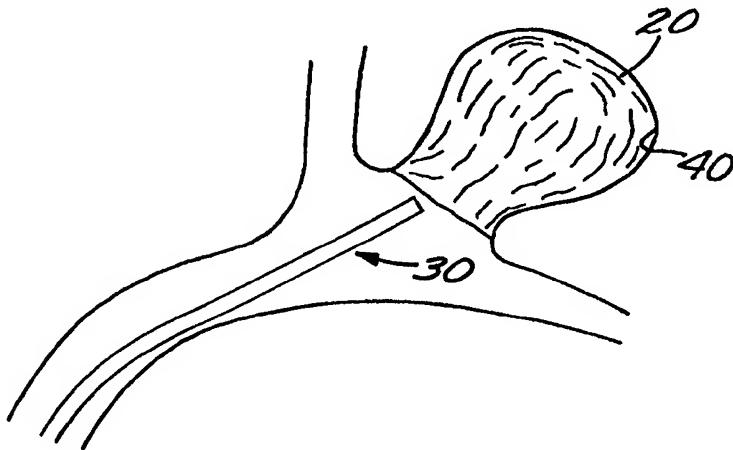
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(54) Title: EXPANSIBLE IMPLANT FOR VASCULAR EMBOLIZATION AND METHOD OF MAKING THE SAME

(57) Abstract

A vascular implant formed of a compressible foam material has a compressed configuration from which it is expandable into a configuration substantially conforming to the shape and size of a vascular site to be embolized. Preferably, the implant is formed of a hydrophilic, macroporous foam material, having an initial configuration of a scaled-down model of the vascular site, from which it is compressible into the compressed configuration. The implant is made by scanning the vascular site to create a digitized scan data set; using the scan data set to create a three-dimensional digitized virtual model of the vascular site; using the virtual model to create a scaled-down physical mold of the vascular site; and using the mold to create a vascular implant in the form of a scaled-down model of the vascular site.



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1 EXPANSIBLE IMPLANT FOR VASCULAR EMBOLIZATION AND METHOD OF MAKING THE SAME

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6 BACKGROUND OF THE INVENTION

7 The present invention relates to the field of methods and devices for the
8 embolization of vascular aneurysms and similar vascular abnormalities. More
9 specifically, the present invention relates to (a) an expandible vascular implant
10 that is inserted into a vascular site such as an aneurysm to create an embolism
11 therein; (b) a method of making the expandible implant; and (c) a method and
12 an apparatus for embolizing a vascular site using the implant.

13 The embolization of blood vessels is desired in a number of clinical
14 situations. For example, vascular embolization has been used to control
15 vascular bleeding, to occlude the blood supply to tumors, and to occlude
16 vascular aneurysms, particularly intracranial aneurysms. In recent years,
17 vascular embolization for the treatment of aneurysms has received much
18 attention. Several different treatment modalities have been employed in the
19 prior art. U.S. Patent No. 4,819,637 - Dormandy, Jr. et al., for example,
20 describes a vascular embolization system that employs a detachable balloon
21 delivered to the aneurysm site by an intravascular catheter. The balloon is
22 carried into the aneurysm at the tip of the catheter, and it is inflated inside the
23 aneurysm with a solidifying fluid (typically a polymerizable resin or gel) to
24 occlude the aneurysm. The balloon is then detached from the catheter by
25 gentle traction on the catheter. While the balloon-type embolization device
26 can provide an effective occlusion of many types of aneurysms, it is difficult
27 to retrieve or move after the solidifying fluid sets, and it is difficult to visualize
28 unless it is filled with a contrast material. Furthermore, there are risks of
29 balloon rupture during inflation and of premature detachment of the balloon
30 from the catheter.

1 Another approach is the direct injection of a liquid polymer embolic
2 agent into the vascular site to be occluded. One type of liquid polymer used in
3 the direct injection technique is a rapidly polymerizing liquid, such as a
4 cyanoacrylate resin, particularly isobutyl cyanoacrylate, that is delivered to the
5 target site as a liquid, and then is polymerized *in situ*. Alternatively, a liquid
6 polymer that is precipitated at the target site from a carrier solution has been
7 used. An example of this type of embolic agent is a cellulose acetate polymer
8 mixed with bismuth trioxide and dissolved in dimethyl sulfoxide (DMSO).
9 Another type is ethylene glycol copolymer dissolved in DMSO. On contact
10 with blood, the DMSO diffuses out, and the polymer precipitates out and
11 rapidly hardens into an embolic mass that conforms to the shape of the
12 aneurysm. Other examples of materials used in this "direct injection" method
13 are disclosed in the following U.S. Patents: 4,551,132 - Pásztor et al.;
14 4,795,741 - Leshchiner et al.; 5,525,334 - Ito et al.; and 5,580,568 - Greff et al.

15 The direct injection of liquid polymer embolic agents has proven
16 difficult in practice. For example, migration of the polymeric material from
17 the aneurysm and into the adjacent blood vessel has presented a problem. In
18 addition, visualization of the embolization material requires that a contrasting
19 agent be mixed with it, and selecting embolization materials and contrasting
20 agents that are mutually compatible may result in performance compromises
21 that are less than optimal. Furthermore, precise control of the deployment of
22 the polymeric embolization material is difficult, leading to the risk of improper
23 placement and/or premature solidification of the material. Moreover, once the
24 embolization material is deployed and solidified, it is difficult to move or
25 retrieve.

26 Another approach that has shown promise is the use of thrombogenic
27 microcoils. These microcoils may be made of a biocompatible metal alloy
28 (typically platinum and tungsten) or a suitable polymer. If made of metal, the

1 coil may be provided with Dacron fibers to increase thrombogenicity. The
2 coil is deployed through a microcatheter to the vascular site. Examples of
3 microcoils are disclosed in the following U.S. patents: 4,994,069 - Ritchart et
4 al.; 5,133,731 - Butler et al.; 5,226,911 - Chee et al.; 5,312,415 - Palermo;
5 5,382,259 - Phelps et al.; 5,382,260 - Dormandy, Jr. et al.; 5,476,472 -
6 Dormandy, Jr. et al.; 5,578,074 - Mirigian; 5,582,619 - Ken; 5,624,461 -
7 Mariant; 5,645,558 - Horton; 5,658,308 - Snyder; and 5,718,711 - Berenstein
8 et al.

9 The microcoil approach has met with some success in treating small
10 aneurysms with narrow necks, but the coil must be tightly packed into the
11 aneurysm to avoid shifting that can lead to recanalization. Microcoils have
12 been less successful in the treatment of larger aneurysms, especially those with
13 relatively wide necks. A disadvantage of microcoils is that they are not easily
14 retrievable; if a coil migrates out of the aneurysm, a second procedure to
15 retrieve it and move it back into place is necessary. Furthermore, complete
16 packing of an aneurysm using microcoils can be difficult to achieve in
17 practice.

18 A specific type of microcoil that has achieved a measure of success is
19 the Guglielmi Detachable Coil ("GDC"). The GDC employs a platinum wire
20 coil fixed to a stainless steel guidewire by a solder connection. After the coil
21 is placed inside an aneurysm, an electrical current is applied to the guidewire,
22 which heats sufficiently to melt the solder junction, thereby detaching the coil
23 from the guidewire. The application of the current also creates a positive
24 electrical charge on the coil, which attracts negatively-charged blood cells,
25 platelets, and fibrinogen, thereby increasing the thrombogenicity of the coil.
26 Several coils of different diameters and lengths can be packed into an
27 aneurysm until the aneurysm is completely filled. The coils thus create and
28 hold a thrombus within the aneurysm, inhibiting its displacement and its

1 fragmentation.

2 The advantages of the GDC procedure are the ability to withdraw and
3 relocate the coil if it migrates from its desired location, and the enhanced
4 ability to promote the formation of a stable thrombus within the aneurysm.
5 Nevertheless, as in conventional microcoil techniques, the successful use of
6 the GDC procedure has been substantially limited to small aneurysms with
7 narrow necks.

8 Still another approach to the embolization of an abnormal vascular site
9 is the injection into the site of a biocompatible hydrogel, such as poly (2-
10 hydroxyethyl methacrylate) ("pHEMA" or "PHEMA"); or a polyvinyl alcohol
11 foam ("PAF"). See, e.g., Horák et al., "Hydrogels in Endovascular
12 Embolization. II. Clinical Use of Spherical Particles", *Biomaterials*, Vol. 7, pp.
13 467-470 (Nov., 1986); Rao et al., "Hydrolysed Microspheres from Cross-
14 Linked Polymethyl Methacrylate", *J. Neuroradiol.*, Vol. 18, pp. 61-69 (1991);
15 Latchaw et al., "Polyvinyl Foam Embolization of Vascular and Neoplastic
16 Lesions of the Head, Neck, and Spine", *Radiology*, Vol. 131, pp. 669-679
17 (June, 1979). These materials are delivered as microparticles in a carrier fluid
18 that is injected into the vascular site, a process that has proven difficult to
19 control.

20 A further development has been the formulation of the hydrogel
21 materials into a preformed implant or plug that is installed in the vascular site
22 by means such as a microcatheter. See, e.g., U.S. Patent Nos. 5,258,042 -
23 Mehta and 5,456,693 - Conston et al. These types of plugs or implants are
24 primarily designed for obstructing blood flow through a tubular vessel or the
25 neck of an aneurysm, and they are not easily adapted for precise implantation
26 within a sack-shaped vascular structure, such as an aneurysm, so as to fill
27 substantially the entire volume of the structure.

28 There has thus been a long-felt, but as yet unsatisfied need for an

1 aneurysm treatment device and method that can substantially fill aneurysms of
2 a large range of sizes, configurations, and neck widths with a thrombogenic
3 medium with a minimal risk of inadvertent aneurysm rupture or blood vessel
4 wall damage. There has been a further need for such a method and device that
5 also allow for the precise locational deployment of the medium, while also
6 minimizing the potential for migration away from the target location. In
7 addition, a method and device meeting these criteria should also be relatively
8 easy to use in a clinical setting. Such ease of use, for example, should
9 preferably include a provision for good visualization of the device during and
10 after deployment in an aneurysm.

11 SUMMARY OF THE INVENTION

12 Broadly, a first aspect of the present invention is a device for occluding
13 a vascular site, such as an aneurysm, comprising a conformal vascular implant,
14 formed of an expandable material, that is compressible from an initial
15 configuration for insertion into the vascular site by means such as a
16 microcatheter while the implant is in a compressed configuration, and that is
17 expandable *in situ* into an expanded configuration in which it substantially fills
18 the vascular site, thereby to embolize the site, wherein the initial configuration
19 of the implant is a scaled-down model of the vascular site.

20 In a preferred embodiment, the implant is made of a hydrophilic,
21 macroporous, polymeric, hydrogel foam material, in particular a water-
22 swellable foam matrix formed as a macroporous solid comprising a foam
23 stabilizing agent and a polymer or copolymer of a free radical polymerizable
24 hydrophilic olefin monomer cross-linked with up to about 10% by weight of a
25 multiolefin-functional cross-linking agent. The material is modified, or
26 contains additives, to make the implant visible by conventional imaging
27 techniques.

28 Another aspect of the present invention is a method of manufacturing a

1 vascular implant, comprising the steps of: (a) imaging a vascular site by
2 scanning the vascular site to create a digitized scan data set; (b) using the scan
3 data set to create a three-dimensional digitized virtual model of the vascular
4 site; and (c) forming a vascular implant device in the form of a physical model
5 of the vascular site, using the virtual model, the implant being formed of a
6 compressible and expandable biocompatible foam material. In a specific
7 embodiment, the forming step (c) comprises the substeps of: (c)(1) using the
8 virtual model to create a scaled-down, three-dimensional physical mold of the
9 vascular site; and (c)(2) using the mold to create a vascular implant in the form
10 of a scaled-down physical model of the vascular site.

11 In the preferred embodiment of the method of manufacturing the
12 implant, the imaging step is performed with a scanning technique such as
13 computer tomography (commonly called "CT" or "CAT"), magnetic resonance
14 imaging (MRI), magnetic resonance angiography (MRA), or ultrasound.
15 Commercially-available software, typically packaged with and employed by
16 the scanning apparatus, reconstructs the scan data set created by the imaging
17 into the three-dimensional digitized model of the vascular site. The digitized
18 model is then translated, by commercially-available software, into a form that
19 is useable in a commercially available CAD/CAM program to create the
20 scaled-down physical mold by means of stereolithography. A suitable implant
21 material, preferably a macroporous hydrogel foam material, is injected in a
22 liquid or semiliquid state into the mold. Once solidified, the hydrogel foam
23 material is removed from the mold as an implant in the form of a scaled-down
24 physical model of the vascular site.

25 A third aspect of the present invention is a method for embolizing a
26 vascular site, comprising the steps of: (a) passing a microcatheter
27 intravascularly so that its distal end is in a vascular site; (b) providing a
28 vascular implant in the form of a scaled-down physical model of the vascular

1 site, the implant being formed of a compressible and expansible biocompatible
2 foam material; (c) compressing the implant into a compressed configuration
3 dimensioned to pass through a microcatheter; (d) passing the implant, while it
4 is in its compressed configuration, through the microcatheter so that the
5 implant emerges from the distal end of the microcatheter into the vascular site;
6 and (e) expanding the implant *in situ* substantially to fill the vascular site.

7 The apparatus employed in the embolization method comprises an
8 elongate, flexible deployment element dimensioned to fit axially within an
9 intravascular microcatheter; a filamentous implant retention element disposed
10 axially through the deployment element from its proximal end to its distal end;
11 and an implant device removably attached to the distal end of the retention
12 element.

13 The implant device, in its preferred embodiment, is formed of a
14 moldable, hydrophilically expansible, biocompatible foam material that has an
15 initial configuration in the form of a scaled-down physical model of the
16 vascular site, that is compressible into a compressed configuration that fits
17 within the microcatheter, and that is hydrophilically expansible into an
18 expanded configuration in which it is dimensioned substantially to conform to
19 and fill the vascular site. Alternatively, the implant device may be formed of a
20 non-hydrophilic foam material having an initial configuration that is
21 substantially the same size and shape as the vascular site, and that restores
22 itself to its initial configuration after it is released from its compressed
23 configuration.

24 The retention element is preferably a flexible wire having a distal end
25 configured to releasably engage the implant device while the implant device is
26 in its compressed configuration, thus to retain the implant device within the
27 distal end of the microcatheter while the distal end of the microcatheter is
28 inserted into the vascular site. The wire is movable axially with the

1 deployment element in the distal direction to expose the implant from the
2 distal end of the microcatheter, and is movable proximally with respect to the
3 deployment element to urge the implant device against the distal end of the
4 deployment element, thereby push the implant device off of the wire. Thus
5 released into the vascular site, the implant device expands into an expanded
6 configuration in which it substantially conforms to and fills the vascular site.

7 The present invention provides a number of significant advantages.
8 Specifically, the present invention provides an effective vascular embolization
9 implant that can be deployed within a vascular site with excellent locational
10 control, and with a lower risk of vascular rupture, tissue damage, or migration
11 than with prior art implant devices. Furthermore, the implant device, by being
12 modelled on the actual vascular site in which it is to be implanted, effects a
13 conformal fit within the site that promotes effective embolization, and yet its
14 ability to be delivered to the site in a highly compressed configuration
15 facilitates precise and highly controllable deployment with a microcatheter. In
16 addition, the method of fabricating the implant device, by modeling it on each
17 individual site, allows implant devices to be made that can effectively
18 embolize vascular sites having a wide variety of sizes, configurations, and (in
19 the particular case of aneurysms) neck widths. These and other advantages
20 will be readily appreciated from the detailed description that follows.

21 BRIEF DESCRIPTION OF THE DRAWINGS

22 Figure 1 is a flow chart showing a method of manufacturing a vascular
23 implant in accordance with a preferred embodiment of the manufacturing
24 method aspect of the present invention;

25 Figure 2 is a perspective view of a vascular implant in accordance with
26 a preferred embodiment of the vascular implant device aspect of the present
27 invention, showing the implant in its initial configuration;

28 Figure 3 is an elevational view of the implant of Figure 2, showing the

1 implant in its compressed configuration;

2 Figure 4 is a perspective view of the implant of Figure 2, showing the
3 implant in its expanded configuration;

4 Figure 5 is a cross-sectional view of an implanting apparatus employed
5 in a method of embolizing a vascular site in accordance with a preferred
6 embodiment of the embolizing method aspect of the present invention; and

7 Figures 6 through 10 are semischematic views showing the steps in a
8 method of embolizing a vascular site (specifically, an aneurysm) in accordance
9 with a preferred embodiment of the embolizing method aspect of the present
10 invention.

11 DETAILED DESCRIPTION OF THE INVENTION

12 The Method of Manufacturing a Vascular Implant. A first aspect of the
13 present invention is a method of manufacturing a vascular implant device.
14 The steps of a preferred embodiment of the manufacturing method are shown
15 as a sequence of descriptive boxes in the flow chart of Figure 1.

16 The first step, shown in box 10 of Figure 1, is the step of creating an
17 image of a vascular site, such as an aneurysm, in which an embolizing implant
18 is to be installed. This imaging step is performed by scanning the site using
19 any of several conventional imaging techniques, such as computer
20 tomography, magnetic resonance imaging (MRI), magnetic resonance
21 angiography (MRA), or ultrasound.

22 The result of the imaging step is a digitized scan data set that is stored
23 in a computer memory, from which the data set is retrieved for operation of
24 the next step: computerized reconstruction of a three-dimensional digitized
25 virtual model of the vascular site (box 12 of Figure 1). This step of creating a
26 three-dimensional digital model is typically performed by software designed
27 for this purpose that is packaged with and employed by the imaging apparatus.

1 The digitized, three-dimensional virtual model is then translated into a
2 form in which it can be employed in a commercially-available CAD/CAM
3 program (box 14) which controls a stereolithography process (box 16) to
4 create a mold for forming an implant device. The translation of the virtual
5 model is performed by software that is commercially available, for example,
6 from Cyberform International, Inc., of Richardson, Texas, and from Stratasys,
7 Inc., of Minneapolis, Minnesota. The mold (not shown) is preferably scaled-
8 down from the dimensions of the vascular site, with a scale of about 1:2 to
9 about 1:6, with about 1:4 being preferred. Alternatively, the mold may be
10 made "life size" (i.e., 1:1); that is, a full-size or nearly full-size replica of the
11 vascular site. The mold is used in the fabrication of a vascular implant device
12 by conventional molding techniques (box 18).

13 The Implant Device. A vascular implant device 20, in accordance with
14 the present invention, is shown in Figure 2 as it appears in its uncompressed or
15 precompressed initial configuration after withdrawal from the mold.

16 Preferably, the implant device 20 is molded directly onto the distal end portion
17 of an elongate, flexible, filamentous retention element, such as a retention wire
18 22, for purposes to be described below. The retention wire 22 preferably has a
19 distal end that terminates in a knob 24 (Figure 5) for better retention of the
20 implant device 20 thereon.

21 In the preferred embodiment, the implant device 20 is made of a
22 biocompatible, macroporous, hydrophilic hydrogel foam material, in particular
23 a water-swellable foam matrix formed as a macroporous solid comprising a
24 foam stabilizing agent and a polymer or copolymer of a free radical
25 polymerizable hydrophilic olefin monomer cross-linked with up to about 10%
26 by weight of a multiolefin-functional cross-linking agent. A suitable material
27 of this type is described in U.S. Patent No. 5,570,585 - Park et al., the
28 disclosure of which is incorporated herein by reference. Another suitable

1 material is a porous hydrated polyvinyl alcohol foam (PAF) gel prepared from
2 a polyvinyl alcohol solution in a mixed solvent consisting of water and a
3 water-miscible organic solvent, as described, for example, in U.S. Patent No.
4 4,663,358 - Hyon et al., the disclosure of which is incorporated herein by
5 reference. Still another suitable material is PHEMA, as discussed in the
6 references cited above. See, e.g., Horák et al., *supra*, and Rao et al., *supra*.
7 The foam material preferably has a void ratio of at least about 90%, and its
8 hydrophilic properties are such that it has a water content of at least about 90%
9 when fully hydrated.

10 In a preferred embodiment, the implant device 20, in its initial,
11 precompressed configuration, will have the same configuration as the vascular
12 site, but it will be smaller, by a factor of approximately two to approximately
13 six. The material of the implant device 20, and its initial size, are selected so
14 that the implant device 20 is swellable or expansible to approximately the size
15 of the vascular site, primarily by the hydrophilic absorption of water molecules
16 from blood plasma, and secondarily by the filling of its pores with blood. The
17 result is an expanded configuration for the implant device 20, as shown in
18 Figure 4, that is large enough substantially to fill the vascular site.

19 Alternatively, the implant 20 device can be molded so that in its initial,
20 precompressed configuration, it is "life size", i.e., approximately the same size
21 as the vascular site. In this case, the preferred material is a compressible, non-
22 hydrophilic polymeric foam material, such as polyurethane. In actual clinical
23 practice, a non-hydrophilic implant device 20 would advantageously be made
24 slightly smaller than actual life size, to accommodate swelling due to the
25 filling of the pores.

26 The foam material of the implant device 20, whether hydrophilic or
27 non-hydrophilic, is advantageously modified, or contains additives, to make
28 the implant 20 visible by conventional imaging techniques. For example, the

1 foam can be impregnated with a water-insoluble radiopaque material such as
2 barium sulfate, as described by Thanoo et al., "Radiopaque Hydrogel
3 Microspheres", *J. Microencapsulation*, Vol. 6, No. 2, pp. 233-244 (1989).
4 Alternatively, the hydrogel monomers can be copolymerized with radiopaque
5 materials, as described in Horák et al., "New Radiopaque PolyHEMA-Based
6 Hydrogel Particles", *J. Biomedical Materials Research*, Vol. 34, pp. 183-188
7 (1997).

8 Whatever the material from which the implant device 20 is made, the
9 implant device 20 must be compressible to a fraction of its initial size,
10 preferably into a substantially cylindrical or lozenge-shaped configuration, as
11 shown in Figure 3. Compression of the implant device 20 can be performed
12 by squeezing it or crimping it with any suitable fixture or implement (not
13 shown), and then "setting" it in its compressed configuration by heating and/or
14 drying, as is well-known. The purpose for this compression will be explained
15 below in connection with the method of using the implant device 20 to
16 embolize a vascular site.

17 The Method and Apparatus for Embolizing a Vascular Site. The
18 method of embolizing a vascular site using the implant device 20 is performed
19 using an implanting apparatus 30, a preferred embodiment of which is shown
20 in Figure 5. The implanting apparatus 30 comprises the retention element or
21 wire 22, a microcatheter 32, and an elongate, flexible, hollow, tubular element
22 34 (preferably a coil) that functions as an implant deployment element, as will
23 be described below. With the implant device 20 attached to the distal end of
24 the retention wire 22, the proximal end of the retention wire 22 is inserted into
25 the distal end of the implant deployment element 34 and threaded axially
26 through the implant deployment element 34 until the proximal end of the
27 implant device 20 seats against, or is closely adjacent to, the distal end of the
28 implant deployment element 34. The implant deployment element 34 is

1 dimensioned for passing axially through the microcatheter 32. Thus, the
2 implant deployment element 34, with the implant device 20 extending from its
3 proximal end, may be inserted into the proximal end (not shown) of the
4 microcatheter 32 and passed axially therethrough until the implant device 20
5 emerges from the distal end of the microcatheter 32, as shown in Figure 5.

6 The implant device 20, in its compressed configuration, has a maximum
7 outside diameter that is less than the inside diameter of the microcatheter 32,
8 so that the implant device 20 can be passed through the microcatheter 32. The
9 implant device 20 is preferably compressed and "set", as described above,
10 before it is inserted into the microcatheter 32.

11 Figures 6 through 10 illustrate the steps employed in the method of
12 embolizing a vascular site 40 using the implant device 20. The vascular site
13 40 shown in the drawings is a typical aneurysm, but the invention is not
14 limited to any particular type of vascular site to be embolized.

15 First, as shown in Figure 6, the microcatheter 32 is threaded
16 intravascularly, by conventional means, until its distal end is situated within
17 the vascular site 40. This threading operation is typically performed by first
18 introducing a catheter guidewire (not shown) along the desired microcatheter
19 path, and then feeding the microcatheter 32 over the catheter guidewire until
20 the microcatheter 32 is positioned substantially as shown in Figure 6. The
21 catheter guidewire is then removed.

22 The implant deployment element 34, with the implant device 20
23 extending from its distal end, is then passed through the microcatheter 32, as
24 described above, until the implant device 20 emerges from the distal end of the
25 microcatheter 32 into the vascular site 40, as shown in Figures 7 and 8. When
26 inserting the implant device 20 into the microcatheter 32, a biocompatible non-
27 aqueous fluid, such as polyethylene glycol, may be injected into the
28 microcatheter 32 to prevent premature expansion of the implant device 20 due

1 to hydration, and to reduce friction with the interior of the microcatheter 32.
2 The implant device 20 thus being exposed from the microcatheter 32 into the
3 interior of the vascular site 40, the pores of the implant device 20 begin to
4 absorb aqueous fluid from the blood within the vascular site 40 to release its
5 "set", allowing it to begin assuming its expanded configuration, as shown in
6 Figure 9. Then, if the implant device 20 is of a hydrophilic material, it
7 continues to expand due to hydrophilic hydration of the implant material, as
8 well as from the filling of its pores with blood. If the implant device 20 is of a
9 non-hydrophilic material, its expansion is due to the latter mechanism only.

10 Finally, when the expansion of the implant device 20 is well underway
11 (and not necessarily when it is completed), the retention wire 22 is pulled
12 proximally with respect to the implant deployment element 34, causing the
13 implant device to be pushed off the end of the installation wire 22 by means of
14 the pressure applied to it by the distal end of the implant deployment element
15 34. The implant device 20, now free of the implanting apparatus 30, as shown
16 in Figure 10, may continue to expand until it substantially fills the vascular site
17 40. The implanting apparatus 30 is then removed, leaving the implant device
18 20 in place to embolize the vascular site 40.

19 While a preferred embodiment of the invention has been described
20 above, a number of variations and modifications may suggest themselves to
21 those skilled in the pertinent arts. For example, instead of custom-fabricating
22 the implant device for each patient, implant devices in a variety of "standard"
23 sizes and shapes may be made, and a particular implant device then selected
24 for a patient based on the imaging of the vascular site. In this case, the
25 fabrication method shown in Figure 1 would be modified by first creating a
26 three-dimensional digital model for each standardized implant, (box 12), and
27 then proceeding with the subsequent steps shown in boxes 14, 16, and 18.
28 Imaging (box 10) would be performed as an early step in the embolization

1 procedure, followed by the selection of one of the standardized implant
2 devices. This and other variations and modifications are considered within the
3 spirit and scope of the invention, as described in the claims that follow.

1 **WHAT IS CLAIMED IS:**

2 1. A vascular implant device for embolizing a vascular site, the device
3 having a compressed configuration from which it is expandable into an
4 expanded configuration substantially conforming to the shape and size of the
5 vascular site.

6 2. The vascular implant device of Claim 1, wherein the implant device
7 has an initial configuration in which it is in the form of a scaled-down model
8 of the vascular site, and from which it is compressible into the compressed
9 configuration.

10 3. The vascular implant device of Claim 2, wherein the device is
11 formed of a hydrophilic foam material.

12 4. The vascular implant device of Claim 3, wherein the foam material
13 is a macroporous hydrogel foam material.

14 5. The vascular implant device of Claim 1, wherein the implant device
15 is compressible into its compressed configuration from its expanded
16 configuration.

17 6. The vascular implant device of Claim 5, wherein the device is
18 formed of a substantially non-hydrophilic polymeric foam material.

19 7. The vascular implant device of Claim 1, wherein the device is
20 radiopaque.

21 8. A method of manufacturing a vascular implant device for
22 embolizing a vascular site, comprising the steps of:

23 (a) imaging a vascular site by scanning the vascular site to create a
24 digitized scan data set;

25 (b) creating a three-dimensional digitized virtual model of the vascular
26 site using the scan data set; and

27 (c) forming a vascular implant device in the configuration of a physical
28 model of the vascular site, using the virtual model, the implant being formed

1 from a compressible foam material.

2 9. The method of Claim 8, wherein the forming step comprises the
3 steps of:

4 (c)(1) creating a three-dimensional physical mold of the vascular site
5 using the virtual model; and

6 (c)(2) molding a vascular implant in the configuration of a physical
7 model of the vascular site.

8 10. The method of Claim 9, wherein the physical mold created in the
9 step of creating the physical mold is a scaled-down physical mold.

10 11. The method of Claim 10, wherein the implant molded in the
11 molding step is in the form of a scaled-down physical model of the vascular
12 site.

13 12. The method of Claim 8, wherein the imaging step is performed by
14 a technique selected from the group consisting of computer tomography,
15 magnetic resonance imaging, magnetic resonance angiography, and
16 ultrasound.

17 13. The method of Claim 8, wherein the step of creating a virtual
18 model is performed by a computer program.

19 14. The method of Claim 9, wherein the step of creating the mold is
20 performed by a CAD/CAM program.

21 15. The method of Claim 14, wherein the step of creating the mold is
22 performed by stereolithography controlled by the CAD/CAM program.

23 16. The method of Claim 11, wherein the compressible foam material
24 includes a hydrophilically expandable foam material.

25 17. The method of Claim 16, wherein the foam material includes a
26 macroporous hydrogel foam material.

27 18. The method of Claim 9, wherein physical mold created in the step
28 of creating a physical mold is a substantially full size replica of the vascular

1 site.

2 19. The method of Claim 18, wherein the implant molded in the
3 molding step is a substantially full size model of the vascular site.

4 20. The method of Claim 19, wherein the compressible foam material
5 includes a substantially non-hydrophilic polymeric foam material.

6 21. A method of embolizing a vascular site, comprising the steps of:

7 (a) providing a vascular implant in the form of a physical model of the
8 vascular site, the implant being formed of a moldable, compressible foam
9 material;

10 (b) compressing the implant into a compressed configuration; (c)
11 deploying the implant in a vascular site with a microcatheter, while the
12 implant is in its compressed configuration; and

13 (d) expanding the implant *in situ* substantially to fill the vascular site.

14 22. The method of Claim 21, wherein the implant is in the form of a
15 scaled-down model of the vascular site, and wherein the implant is formed of a
16 hydrophilically-expansile foam material.

17 23. The method of Claim 22, wherein the expanding step is performed
18 by the hydrophilic absorption of fluid by the implant.

19 24. The method of Claim 21, wherein the deploying step comprises the
20 steps of:

21 (c)(1) inserting the distal end of the microcatheter into the vascular site;
22 (c)(2) passing the implant through the microcatheter, while the implant
23 is in its compressed configuration, until the implant emerges from the distal
24 end thereof into the vascular site; and

25 (c)(3) releasing the implant, while in its compressed configuration,
26 from the distal end of the microcatheter.

27 25. Apparatus for embolizing a vascular site, comprising:
28 a microcatheter having a distal end and a proximal end;

1 a vascular implant device configured as a model of the vascular site and
2 formed of a compressible foam material, the implant device having a
3 compressed configuration dimensioned to pass through the microcatheter from
4 the proximal end thereof and out of the distal end thereof;

5 a retention element contained within the microcatheter and having a
6 distal end detachably connected to the implant device; and

7 a deployment element operably associated with the retention element
8 and engageable against the implant device so as to separate the implant device
9 from the retention element when the implant device has emerged from the
10 distal end of the microcatheter.

11 26. The apparatus of Claim 25, wherein the deployment element is
12 dimensioned to pass axially through the microcatheter from the proximal end
13 to the distal end thereof, the deployment element having a distal end that is
14 engageable against the implant device; and

15 wherein the retention element is movable with the deployment element
16 when the deployment element is passed through the microcatheter, and is also
17 movable between first and second positions relative to the distal end of the
18 deployment element, whereby the implant device is displaced out of the distal
19 end of the microcatheter when the deployment element is passed through the
20 microcatheter, and whereby the implant device is separated from the retention
21 element when the retention element is moved from the first position to the
22 second position.

23 27. The apparatus of Claim 25, wherein the implant device
24 is initially configured as a scaled-down model of the vascular site and has an
25 expanded configuration in which its substantially conforms to the vascular
26 site.

27 28. The apparatus of Claim 27, wherein the implant device is formed
28 of a hydrophilic, macroporous, polymeric foam material.

- 1 29. The apparatus of Claim 25, wherein the deployment element
- 2 comprises an elongate, flexible, tubular element.
- 3 30. The apparatus of Claim 29, wherein the retention element
- 4 comprises an elongate, flexible, filamentous element disposed axially through
- 5 the tubular element and movable with respect thereto between the first and
- 6 second positions.

1/3

FIG.1

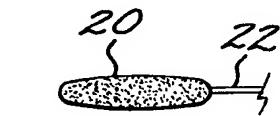
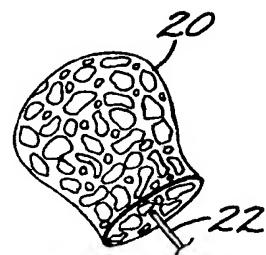
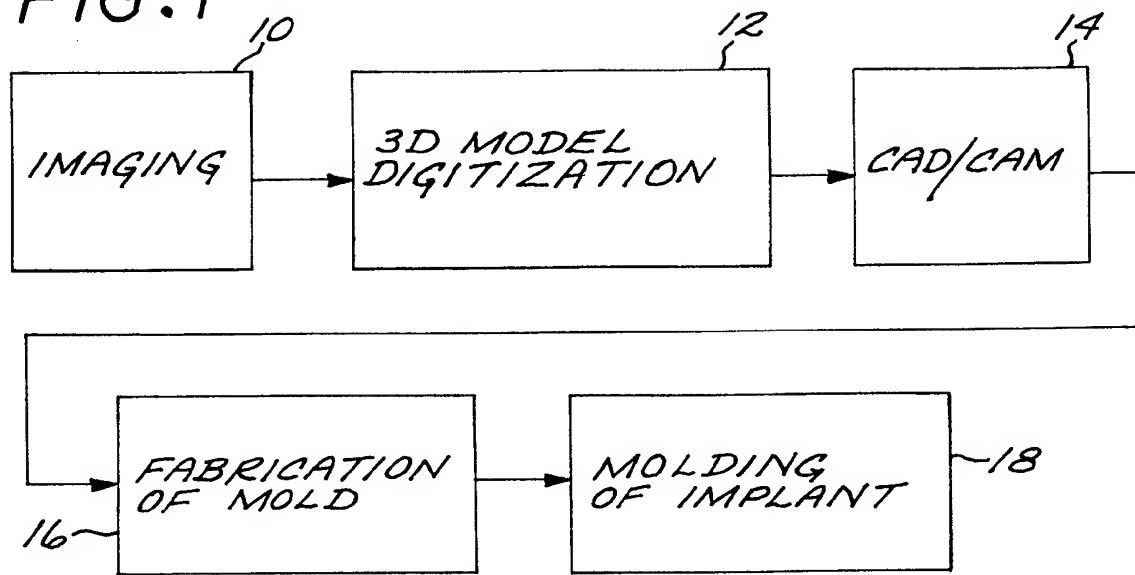


FIG.3

FIG.2

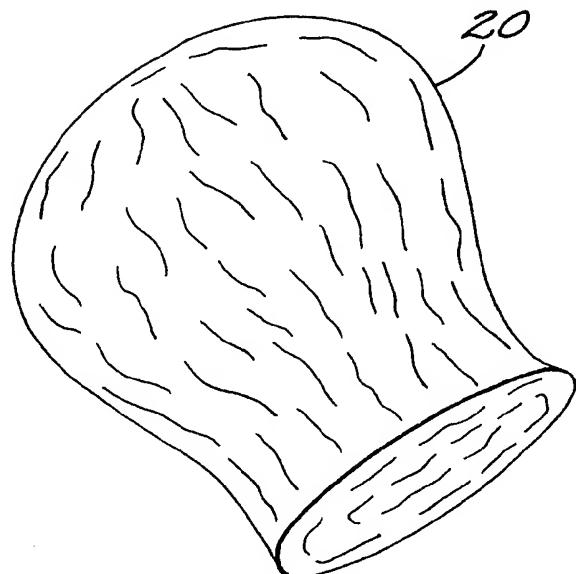


FIG.4

FIG.5

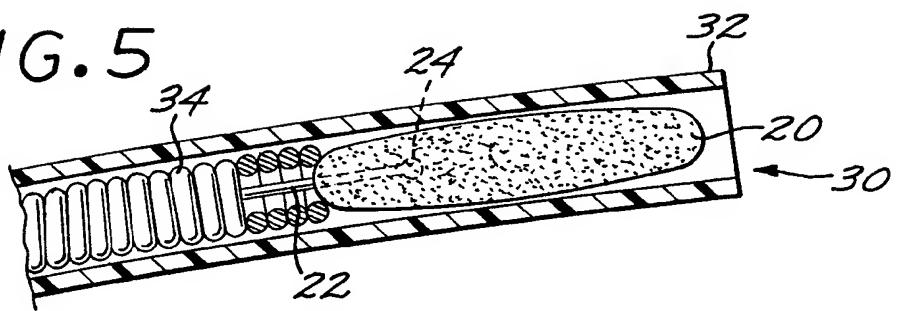


FIG.6

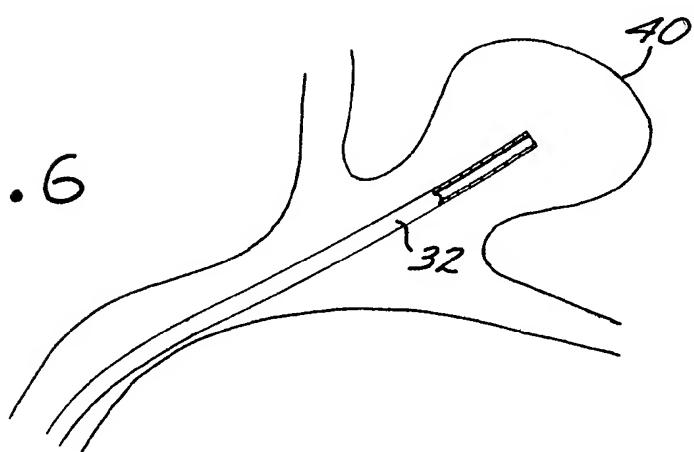


FIG.7

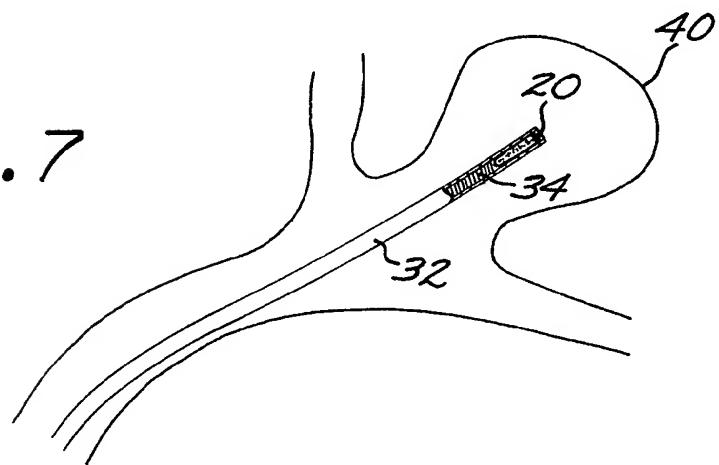


FIG. 8

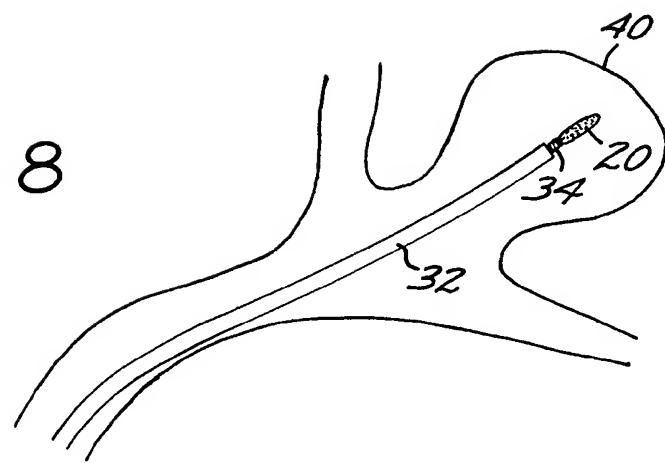


FIG. 9

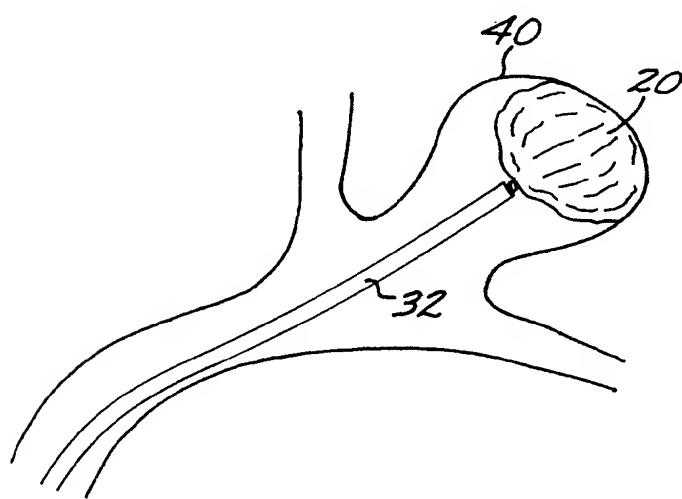
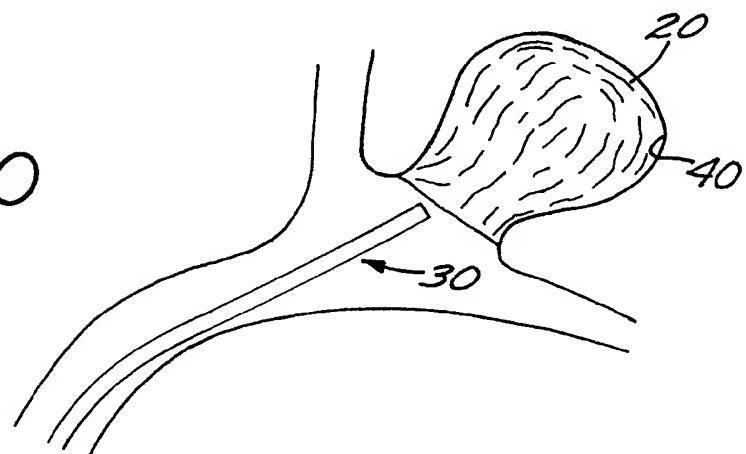


FIG. 10



INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 99/15108

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B17/12

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used);

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 98 04198 A (GREFF RICHARD J ;JONES MICHAEL L (US); MICRO THERAPEUTICS INC (US)) 5 February 1998 (1998-02-05) page 11, line 16 -page 13, line 31; figures 2,6 ---	1-5,7, 25-30
A	WO 89 11257 A (AUGSPURGER LYNN L) 30 November 1989 (1989-11-30) page 10, line 2 -page 11, line 22 abstract; figure 5 ---	8
X	WO 89 11257 A (AUGSPURGER LYNN L) 30 November 1989 (1989-11-30) page 10, line 2 -page 11, line 22 abstract; figure 5 ---	8-20
A	US 5 554 190 A (DRAENERT KLAUS) 10 September 1996 (1996-09-10) abstract; claim 1; figure 1 ---	8-20
A	EP 0 717 969 A (TARGET THERAPEUTICS INC) 26 June 1996 (1996-06-26) abstract; figures 1,4,5 ---	1,8,25
	-/--	

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
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- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- "&" document member of the same patent family

Date of the actual completion of the international search

28 September 1999

Date of mailing of the international search report

04/10/1999

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INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 99/15108

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 750 585 A (PARK HAESUN ET AL) 12 May 1998 (1998-05-12) abstract ---	1,3,4, 25,28
A	EP 0 664 104 A (MICRO THERAPEUTICS INC) 26 July 1995 (1995-07-26) abstract; figures 13A,15A -----	1,8,25

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 99/15108

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.: 21-24
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT – Method for treatment of the human or animal body by surgery
2. Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

The additional search fees were accompanied by the applicant's protest.
 No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members				International Application No PCT/US 99/15108	
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